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UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
J-135CIP

Total Pages in this Submission

TO THE ASSISTANT COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

CONSTITUENT DELIVERY SYSTEM

and invented by:

Jimmie L. JOHNSON

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*

☐ **Continuation** ☐ **Divisional** ☒ **Continuation-in-part (CIP)** of prior application No.: **08/979,028**

Which is a:

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: **08/641,430**

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Enclosed are:

Application Elements

1. ☐ Filing fee as calculated and transmitted as described below

2. ☒ Specification having **13 (thirteen)** pages and including the following:

   a. ☒ Descriptive Title of the Invention
   b. ☐ Cross References to Related Applications *(if applicable)*
   c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   d. ☐ Reference to Microfiche Appendix *(if applicable)*
   e. ☒ Background of the Invention
   f. ☒ Brief Summary of the Invention
   g. ☒ Brief Description of the Drawings *(if drawings filed)*
   h. ☒ Detailed Description
   i. ☒ Claim(s) as Classified Below
   j. ☐ Abstract of the Disclosure

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

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Docket No. J-135CIP
Total Pages in this Submission

Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
   a. ☐ Formal b. ☒ Informal Number of Sheets **1 (one)**

4. ☒ Oath or Declaration
   a. ☐ Newly executed *(original or copy)* ☒ Unexecuted
   b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
   c. ☐ With Power of Attorney ☐ Without Power of Attorney
   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Computer Program in Microfiche

7. ☐ Genetic Sequence Submission *(if applicable, all must be included)*
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☐ Assignment Papers *(cover sheet & documents)*

9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☒ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☐ Certificate of Mailing
    ☐ First Class ☒ Express Mail *(Specify Label No.):* **EL696074397US**

UTILITY PATENT APPLICATION TRANSMITTAL
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(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No. J-135CIP
Total Pages in this Submission

Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: **1 (one)**

17. ☒ Additional Enclosures *(please identify below):*

Inventor Information Sheet (Patent Biological Data)
Copy of Petition for Extension of Time filed in Parent Application

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra		Rate	Fee
Total Claims	22	- 20 =	0	x	$9.00	~~$18~~ ~~$0.00~~
Indep. Claims	2	- 3 =	0	x	$39.00	$0.00
Multiple Dependent Claims (check if applicable) ☐						$0.00
					BASIC FEE	~~$345~~ 363 .00
OTHER FEE *(specify purpose)*						$0.00
					TOTAL FILING FEE	~~$345~~ 363 .00

☐ A check in the amount of to cover the filing fee is enclosed.
☐ The Commissioner is hereby authorized to charge and credit Deposit Account No. as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of as filing fee.
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- ☐ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **August 7, 2000**

Signature

James H. Walters, Reg. No. 35,731
DELLETT AND WALTERS
310 S.W. Fourth Avenue, Suit 1101
Portland, Oregon 97204
(503) 224-0115

cc:

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): **Jimmie L. JOHNSON**			Docket No. **J-135CIP**
Serial No.	Filing Date	Examiner	Group Art Unit

Invention:

CONSTITUENT DELIVERY SYSTEM

I hereby certify that the following correspondence:

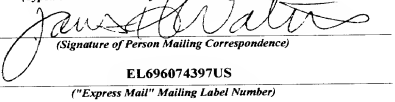
New Patent Application Transmittal (& the documents listed as enclosed thereon.

(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Assistant Commissioner for Patents, Washington, D.C. 20231 on

August 7, 2000
(Date)

James H. Walters
(Typed or Printed Name of Person Mailing Correspondence)



(Signature of Person Mailing Correspondence)

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Note: Each paper must have its own certificate of mailing.

Attorney's Docket No. J-135 **PATENT**

Applicant or Patentee: JIMMIE L. JOHNSON

Serial or Patent No.: 0 /

Filed or Issued:

For: CONSTITUENT DELIVERY SYSTEM

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b))—INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled CONSTITUENT DELIVERY SYSTEM

described in

- ☒ the specification filed herewith.
- ☐ application serial no. 0 / _____, filed _____.
- ☐ patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern, or organization
- ☐ persons, concerns or organizations listed below *

*NOTE: *Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).*

FULL NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Jimmie L. Johnson

Name of inventor

Signature of inventor

Date 23 April 96

Name of inventor

Signature of inventor

Date

Name of inventor

Signature of inventor

Date

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City of Residence:: Chicago
State or Province of Residence:: Illinois
Country of Residence:: US
Citizenship Country:: US

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APPLICATION INFORMATION

Title Line One:: CONSTITUENT DELIVERY SYSTEM
Total Drawing Sheets:: 1
Formal Drawings?:: No
Application Type:: Utility
Docket Number:: J-135CIP
Secrecy Order in Parent Appl.?:: No

REPRESENTATIVE INFORMATION

Representative Customer Number:: 802
Registration Number One:: 35731

CONTINUITY INFORMATION

This application is a:: CONTINUATION IN PART OF
> Application One:: 08/979,028
Filing Date:: 11-26-1997

Which is a::CONTINUATION OF
>> Application Two:: 08/641,430
Filing Date:: 05-01-1996

Which is a::NON PROV. OF PROVISIONAL
>>> Application Three:: 60/004,967
Filing Date:: 10-10-1995

Source:: PrintEFS Version 1.0.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
JIMMIE L. JOHNSON
S. N.
Filed: August 7, 2000
For: CONSTITUENT DELIVERY SYSTEM

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please make the following amendments to this application prior to examination thereof:

In the Specification:

Page 1, between lines 2 and 3, insert the following:
--This is a continuation-in-part of co-pending application S.N. 08/979,028, filed on November 26, 1997, which is a file wrapper continuation of U.S. Patent Application S.N. 08/641,430, filed May 1, 1996, which was a non-provisional of U.S. Provisional Patent Application S.N. 60/004,967, filed October 10, 1995.--

Page 3, line 30, delete "and";

line 32, delete the period "." and insert
--;

FIG. 6 is a view of a preferred embodiment container employing an additional lid for sanitary purposes; and

FIGs. 7-9 are views illustrating the use of the embodiment of FIG. 6.--

Page 6, between lines 27 and 28, please insert the following:

--Referring now to FIG. 6, in a preferred embodiment of a container 48 according to the invention, another lid layer 50 is suitably provided as an outermost lid, on top of outer lid 24. Lid layer 50 is suitably peelable or otherwise removable, by

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lifting a tab member portion 52 thereof in an upwardly direction, to peel the lid away from covering the top layer of lid 24 and stopper portion 32, thereby exposing the syringe receiving stopper portion 32. Lid layer 50 is advantageous in providing an additional sanitary feature, as may be understood in connection with FIGs. 7-9, which are views illustrating the embodiment of FIG. 6 in use. To employ the container 48 of the present invention, the user presses downwardly on the top of lid layer 50, as illustrated in FIG. 7., wherein the user's thumb or finger 54 is shown. The downward pressure causes capsule 28/28' to penetrate lower lid 22, so as to be combined with the constituent 14 within the interior of the container. Next, as shown in FIG. 8, the user peels lid layer 50 away from the top of the cup (either completely removing the layer 50, or leaving it partially attached as shown in FIG. 8). Since the top lid layer 50 was in place when the user pressed on the lid structure to release the capsule, the next layer down, which has the syringe receiving portion 32, is maintained clean and sterile, since it was not touched by the user's finger or thumb (layer 50 provided a sanitary shield between the user and the syringe receiving portion. Now, as shown in FIG. 9, the syringe 42 can be inserted into the interior of the container to draw the contents up into the syringe. Depending on the particular constituents in the container and capsule, it may be desirable to mix the compounds by shaking or the like, prior to withdrawing into the syringe.

While a single capsule 28/28' is shown in the illustrated embodiments, plural such capsule may be employed, when more than two constituents are desirably separated until time of use. --

Line 33, at the end of this line, insert the following: --Also, with the container and system of the invention, an easy to use sanitary injectable constituent container is provided that maintains plural constituents separate until use, while enabling sanitary deployment, mixing and withdrawal of the mixed constituents via a syringe or the like. --

In the Claims:

Please cancel claims 7 and 21-27.

Please amend claims 1-3, 5, 6, 8, 13, 14, 16, 18 as follows

1. (Amended) A constituent delivery system for maintaining a first constituent and a second constituent separate from each other until ready for combining, comprising:

a container [means] for holding the first constituent;

sterile separation [means] member for maintaining said second constituent separate from said first constituent and said first and second constituents sterile relative to the exterior atmosphere; [and]

[introducing means] an introducer for enabling combining of said first and second constituents within said container [means] and maintaining said first and second constituents sterile relative to the exterior atmosphere;

a syringe receiving portion for enabling insertion and removal of a syringe while still maintaining integrity of said sterile separation member; and

a removable cover member for covering at least said syringe receiving portion.

2. (Amended) A constituent delivery system according to claim 1 wherein said sterile separation [means] member comprises a first seal sealing said first constituent within said container and a second seal sealing said first seal and said second constituent from the external atmosphere.

3. (Amended) The constituent delivery system according to claim 2 wherein said introducing [means] member comprises a capsule containing said second constituent.

5. (Amended) The constituent delivery system according to claim 3 wherein said capsule comprises [means] a member for penetrating said first seal, for introducing said second constituent into said first constituent.

6. (Amended) The constituent delivery system according to claim 1 wherein said container [means] comprises well [means] portion whereby, if said first constituent is a liquid, the liquid pools in said well [means] portion as the volume of said liquid is reduced.

8. (Amended) The constituent delivery system according to claim 1 further comprising an indicator [means] for indicating combining of said first and second constituents.

13. (Amended) A constituent storage system for maintaining a first constituent and a second constituent separate from each other until ready for combining, comprising:

a storage [means] container for holding the first and the second constituents sterile relative to the exterior atmosphere;

a barrier [means] for maintaining said second constituent separate from said first constituent within said storage [means] container; [and]

combining means for enabling combining of said first and said second constituents within said storage means and maintaining said first and said second constituents sterile relative to the exterior atmosphere;

a syringe receiving portion for enabling insertion and removal of a syringe while still maintaining integrity of said storage container relative to the external atmosphere; and

a removable cover member for covering said syringe receiving portion.

14. (Amended) A constituent storage system according to claim 13 wherein said barrier [means] comprises a first seal sealing said first constituent within said storage [means] container and a second seal sealing said first seal and said second constituent from the external atmosphere.

16. (Amended) A constituent storage system according to claim 15 wherein said first seal breaks under pressure, thereby introducing said second constituent into said first constituent, while said second seal remains intact, thereby preserving the sterility of the storage [means] container and its contents.

18. (Amended) A constituent storage system according to claim 13 wherein said storage [means] container comprises a well [means] portion whereby said first constituent settles in said well [means] portion as the volume of said first constituent is reduced.

Please add new claims 28 and 29 as follows:

28. A constituent delivery system according to claim 1 wherein said second constituents comprises plural constituents maintained separate from one another until combined with said first constituent.

29. A constituent delivery system according to claim 1 wherein said removable cover member for covering substantially all of a portion of said sterile separation member keeping said first and second constituents sterile relative to the exterior atmosphere

In the Drawings:

Please add new FIGs. 6-9, as shown on the drawing sheet attached hereto.

REMARKS

The above amendment to the specification is presented so the first sentence of the specification will contain a specific reference to the prior applications and so that the application will be in a format consistent with U.S. practice.

Respectfully submitted,

James H. Walters, Reg. No. 35,731

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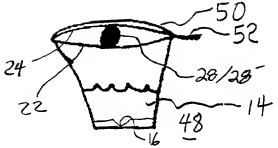

FIG. 6

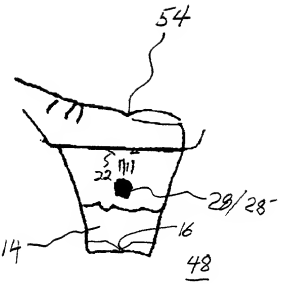

FIG. 7

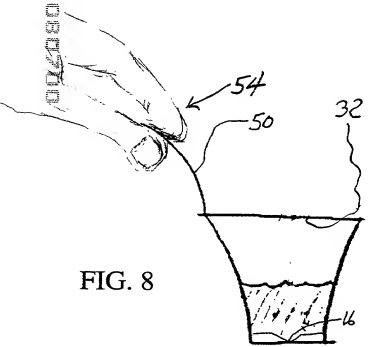

FIG. 8

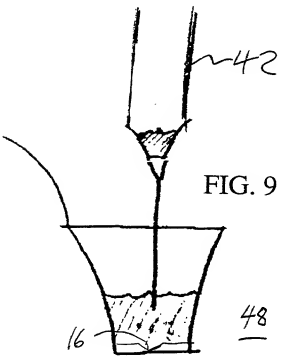

FIG. 9

CONSTITUENT DELIVERY SYSTEM

Background of the Invention

In delivery of items, for example medicine or pharmaceuticals or food stuffs, especially when the items are shipped long distances, in order to ensure a long shelf life of the items, portions are often separated into constituent parts and then recombined just prior to use, for example with medicines such as antibiotics, portions are freeze dried and shipped separately from a sterile liquid component whereupon the liquid portion of the container is sterilized and the dried ingredients are added thereto and mixed and the liquid thus produced is then available for use with a syringe, for injecting into a patient, for example, or for consuming orally if that is the appropriate mode of consumption.

An alternative method of employing such separate constituents which are later mixed is to have both the freeze dried component and the liquid component in separate sterile containers (for example, the liquid component may be in a prefilled syringe and the freeze dried component in a vial which includes a syringe-penetrable top). The vial top is sterilized through use of an alcohol swab, for example, and the syringe is caused to penetrate the top thereof so as to enable injection of the liquid into the vial. The syringe is then suitably withdrawn and the liquid and freeze dried component are mixed to create a well dispersed suspension or until the freeze dried component dissolves whereupon the vial top may again be sterilized through use of an alcohol swab and the liquid pharmaceutical then be withdrawn in the appropriate amount with the syringe, for injection into the patient.

Such systems are at times less than desirable, since the separate shipping or packaging of the various components is prone to situations where one constituent is shipped and separated from the other constituent, resulting in difficulties in keeping the two constituents together. Further, the chance of contamination or infection of the ingredients is greater, since the number of steps where sterility must be maintained is increased, for example, the syringe must be maintained sterile, the contents of the syringe must be maintained in a sterile condition, the freeze dried component must be maintained in a sterile condition and the external surfaces of the containers which may contact various parts of the syringe or the like must also be maintained or made sterile, increasing the chance of contamination. Another drawback arises when the liquid portion is typically provided in bulk and must be measured at the time of reconstituting with sterile measuring. Such remixing may be difficult in field locations which may not have access to sterile conditions.

Summary of the Invention

According to the present invention, a system of at least two constituents is provided in a unitary container wherein a liquid constituent, for example, is contained within a vial which may take the shape of a cup and an inner lid portion seals the liquid constituent within its container. An outer lid is also provided with a space defined between the inner and outer lid wherein the other constituent or constituents are contained within the space therebetween. In use, the other constituent is caused to penetrate the inner lid so as to combine with the liquid ingredient, while the

outer lid is maintained in its sealed state. The constituents are still maintained sterile within the vial or cup. Mixing then occurs whereupon the outer lid may be removed, or alternatively, may be sterilized with an alcohol wipe and a syringe inserted therein.

It is an object of the invention to provide an improved delivery system and method for providing multipart constituents.

It is a further object of the present invention to provide an improved system for providing pharmaceuticals with separated portions while enabling reconstituting the portions in a sterile environment.

It is an object of the present invention to provide an improved method and system for enabling premixing of constituents in premeasured portions prior to use.

Brief Description of the Drawings

FIG. 1 is a cross sectional view of a container according to the present invention for providing two constituents;

FIG. 2 is a cross sectional view of the container of FIG. 1 after the ingredients are combined;

FIG. 3 is a view of the container of FIG. 2 illustrating removal of the now mixed components via use of a syringe;

FIG. 4 is a view of the capsule portion of the container of FIG. 1; and

FIG. 5 is a view of an alternative capsule portion.

Detailed Description

Referring now to FIG. 1, a container 10 in accordance with the present invention comprises a cup-like container 12, which suitably is made of plastic wherein a liquid 14 is contained within the cup. In the illustrated embodiment, the liquid comprises 4-9 ccs in volume. The interior bottom of the cup defines a well 16 therein with inwardly sloping walls so as to ensure that the center 18 of the well is the lowest most point within the interior of the cup or vial 12. The interior of the cup may comprise solid portions 20 which assist in defining the shape of the well.

Near the top of the cup is provided an inner lid 22 which substantially seals the interior of the liquid containing chamber and an outer lid 24 which is also secured to the cup 12 or to the top of bottom lid 22. A central cavity 26 is suitably defined between the top lid 24 and the lower lid 22 wherein a capsule member 28 is positioned within the chamber. The capsule may contain a medicine or freeze dried constituent of an antibiotic, for example, 30 therewithin. In this state, the two constituents 14 and 30 are maintained separate from each other, but are sealed to the outside world so as to ensure sterility. The region of top lid 24 above capsule 28 may suitably comprise a rubber stopper portion 32 of the type employed in vials wherein a syringe may be inserted therein as necessary.

Referring now to FIG. 4, the structure of capsule portion 28 may be observed. The capsule may suitably be of plastic or glass or any other suitable material and includes sharp edge portions 34 and sealed top portion 36, which may also

include a rubberized stopper of the type normally employed in conjunction with vials adapted for use with syringes. The constituent is suitably confined within the capsule, but the bottom of the capsule remains opened. The bottom lid is thus relied upon to keep the medicine within the capsule, since the bottom lid would thus provide the bottom sealing portion to capsule 28.

Referring now to FIG. 2, in use, in order to mix the two constituents, top lid 24 is pushed downwardly in the direction of arrow 38 of FIG. 2 whereupon the sharp edge portions 34 of the capsule puncture the bottom lid. Since the bottom lid is suitably designed to be so punctured, the constituent 30 is released into the liquid 14 whereupon the two are mixed through vigorous shaking if appropriate. Note that the top lid seal has not been broken, so the interior of the cup 12 remains sterile or otherwise unopen to the outside atmosphere.

Referring now to FIG. 3, to retrieve the now mixed ingredients 40, which is the combination of the constituent 30 and 14, a syringe 42 is inserted through region 32 which suitably comprises a rubber stopper or the like as typically employed with syringe receiving vials (suitably after the top thereof is cleansed with an alcohol swipe or the like). The needle 44 of the syringe suitably extends down to the bottom 18 of well 16 so as to enable withdrawal of the maximum amount of the liquid constituent 40 as possible without excessive waste.

It should be noted that the container and its ingredients may be so measured as to either provide single dosage or multiple dose as desired. As an example, ingredients 14 and 30 may comprise a

liquid constituent and a freeze dried antibiotic, vitamin components, or other pharmaceuticals. Also, the items together may comprise certain foodstuffs or the like.

Referring to FIG. 5, an alternative embodiment employs a capsule 28' which is suitably made of an inert ingredient that dissolves in the liquid, such as a gelatin type capsule typically used in the delivery of pharmaceuticals or vitamins. In this embodiment, the ingredient 30 is contained within the capsule and bottom lid portion 22 is sufficiently thin so as to enable the capsule 28' to penetrate through the bottom lid when the top lid is pressed downwardly in the direction of arrow 38 (FIG. 2). The capsule 28' then falls into the liquid portion 14 and suitably dissolves to release ingredient 30 to the liquid for subsequent mixing.

The lid portion 24 is also provided in an alternative embodiment in a deformable plastic which once pressed downwardly retains its deformed shape or becomes discolored so as to enable a determination to be made whether the capsule portion has been depressed into the liquid portion. Thus, on quick inspection, it is possible to determine whether the cup is a fresh unmixed vial or whether it has been previously mixed either intentionally or through damage during shipping.

Accordingly, the present invention provides an improved delivery system and method for providing separate constituents, suitably food or pharmaceutical ingredients, enabling longer shelf life while maintaining sterile conditions and enabling sterile mixing in the field.

Claims

1. A constituent delivery system for maintaining a first constituent and a second constituent separate from each other until ready for combining, comprising:

container means for holding the first constituent;

sterile separation means for maintaining said second constituent separate from said first constituent and said first and second constituents sterile relative to the exterior atmosphere; and

introducing means for enabling combining of said first and second constituents within said container means and maintaining said first and second constituents sterile relative to the exterior atmosphere.

2. A constituent delivery system according to claim 1 wherein said sterile separation means comprises a first seal sealing said first constituent within said container and a second seal sealing said first seal and said second constituent from the external atmosphere.

3. The constituent delivery system according to claim 2 wherein said introducing means comprises a capsule containing said second constituent.

4. The constituent delivery system according to claim 3 wherein said first seal breaks under pressure, thereby introducing said capsule into said first constituent, while said second seal remains intact, thereby preserving sterility of the container and its contents.

5. The constituent delivery system according to claim 3 wherein said capsule comprises means for penetrating said first seal, for introducing said second constituent into said first constituent.

6. The constituent delivery system according to claim 1 wherein said container means comprises well means whereby, if said first constituent is a liquid, the liquid pools in said well means as the volume of said liquid is reduced.

7. The constituent delivery system according to claim 1 further comprising syringe receiving means for enabling insertion and removal of a syringe while still maintaining integrity of said sterile separation means.

8. The constituent delivery system according to claim 1 further comprising indicator means for indicating combining of said first and second constituents.

9. The constituent delivery system according to claim 1 wherein said first constituent is in liquid form.

10. The constituent delivery system according to claim 1 wherein said second constituent is in a non-liquid form.

11. The constituent delivery system according to claim 1 wherein said first and second constituents when combined comprise a medicinal preparation.

12. The constituent delivery system according to claim 11 wherein said medicinal preparation comprises an antibiotic.

13. A constituent storage system for maintaining a first constituent and a second constituent separate from each other until ready for combining, comprising:

storage means for holding the first and the second constituents sterile relative to the exterior atmosphere;

barrier means for maintaining said second constituent separate from said first constituent within said storage means; and

combining means for enabling combining of said first and said second constituents within said storage means and maintaining said first and said second constituents sterile relative to the exterior atmosphere.

14. A constituent storage system according to claim 13 wherein said barrier means comprises a first seal sealing said first constituent within said storage means and a second seal sealing said first seal and said second constituent from the external atmosphere.

15. A constituent storage system according to claim 13 wherein said combining means comprises a capsule containing said second constituent.

16. A constituent storage system according to claim 15 wherein said first seal breaks under pressure, thereby introducing said second constituent into said first constituent, while said

second seal remains intact, thereby preserving the sterility of the storage means and its contents.

17. A constituent storage system according to claim 15 wherein said capsule comprises means for penetrating said first seal, for introducing said second constituent into said first constituent.

18. A constituent storage system according to claim 13 wherein said storage means comprises well means whereby said first constituent settles in said well means as the volume of said first constituent is reduced.

19. A constituent storage system according to claim 13 further comprising syringe receiving means for enabling insertion and removal of a syringe while still maintaining the sterility of said storage means.

20. A constituent storage system according to claim 13 further comprising indicator means for indicating introduction of said first constituent to said second constituent.

21. A method of combining a first constituent and a second constituent held separate from each other until ready for combining, comprising:

providing a first constituent in a container means;

providing sterile separation means for maintaining a second constituent separate from said first constituent and initially maintaining

said first and second constituents sterile relative to the exterior atmosphere;

providing introducing means for enabling combining of said first and second constituents within said container means and further maintaining said first and second constituents sterile relative to the exterior atmosphere; and

exerting a force on said introducing means thereby to combine said first and second constituents while maintaining said first and second constituents sterile relative to the external atmosphere.

22. The method according to claim 21 wherein said sterile separation means comprises a first seal sealing said first constituent within said container and a second seal sealing said first seal and said second constituent from the external atmosphere, and wherein the step of exerting a force on said introducing means comprises puncturing said first seal.

23. The method of claim 22 wherein said introducing means comprises a capsule containing said second constituent, and wherein the step of exerting a force on said introducing means comprises pressing the capsule through said first seal.

24. The method according to claim 22 wherein said introducing means comprises sharp edge portions and wherein the step of exerting a force comprises forcing said sharp edge portions to puncture said first seal.

25. The method of claim 21 further comprising shaking the container means to mix together the first and second constituents.

26. The method according to claim 21 further comprising inserting a syringe needle into said container means to draw the first and second constituents into a syringe through said syringe needle.

27. The method according to claim 21 further comprising providing an indicator means for indicating the combining of said first and second constituents.

Abstract

A constituent delivery vial and method employs a sealed vial portion which employs an inner lid to keep a first constituent, suitably a liquid, separate from a second constituent. The second constituent is contained within a capsule wherein the capsule is maintained within a chamber between the first lid and an outer top lid. The constituents are mixed by depressing the top lid to cause the capsule to penetrate the bottom lid and either directly release the constituent containers in the capsule to the constituent contained below the lower lid or, in the case of a dissolving capsule, to allow combining of the two once the capsule dissolves. The bottom of the cup includes a syringe well which slopes downwardly to provide a central lowest point to the cup to enable use of a syringe for retrieval of as much of the mixed constituents as possible.

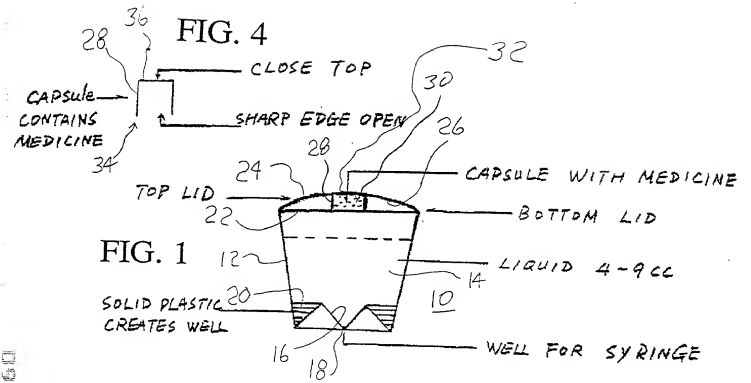

FIG. 4

FIG. 1

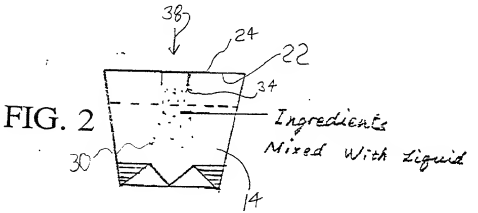

FIG. 2

FIG. 5

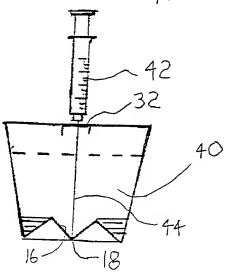

FIG. 3

Docket No.
J-135CIP

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CONSTITUENT DELIVERY SYSTEM

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

60/004,967	October 10, 1995
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

08/979,028	November 26, 1997	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
08/641,430	May 1, 1996	Abandoned
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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